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| 09/235,416 | 01/22/99 | SAKOWICZ | R 18557C-7-1 |

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| **ART UNIT** | **PAPER NUMBER** |
| 1645 | 13 |

**DATE MAILED:** 09/07/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 09/235,416 | Applicant(s) Sakowicz et al |
|---|---|---|
| | Examiner Li Lee | Group Art Unit 1645 |

☒ Responsive to communication(s) filed on *Jul 24, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claim**

☒ Claim(s) *1-58* is/are pending in the applicat

Of the above, claim(s) *1-33 and 47-58* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *34-46* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4 and 6*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election with traverse of Group V, claims 34-46 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that groups I-VIII are from a common concept and theory, and thus related. As such, prosecution of the claims of Groups I-VIII would not place a substantially greater burden on the Examiner. These arguments have been fully considered but not found to be persuasive for the reasons below.

MPEP 803 states that restriction is proper between patentable distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required. In the instant situation, the inventions of Groups I-VIII are drawn to distinct inventions which are described in the previous Office Action. Restrictions between the inventions is deemed to be proper for the reasons previously set forth. In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of Groups I-VIII are classified separately necessitating different searches of issued U.S. Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because, for example, a search for the claims of group I, DNA or for the claims of group VI, a computer system does not encompass the search for the group V, a method for

screening modulators. Additionally, it is submitted that the inventions of Groups I-VIII have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group. For reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 34-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34-46 are indefinite in the use of abbreviation TL-γ in claims 34 and 44 without identification of the meaning of the abbreviation. Amendment of claims 34-46 to use the full name of the abbreviation would obviate this rejection. Claim 34 recites the limitation "the protein's activity" in lines 5 and 7. There is insufficient antecedent basis for this limitation in the claim. Claim 34 is further indefinite for using the term "control concentration" which is not clear what limitation is implied by the recitation, such might indicate that the claimed candidate agent is present in a controlled concentration, or alternatively might be intended to indicate that there is a positive control present in the test.

Claims 35-42 and 44-46 are indefinite for using the terms "A method" in claims 35-42 and "A kit" in claims 44-46, respectively. It is not clearly if applicants intend to claim one method or one kit, or alternatively to indicate that there is more than one method or more than one kit being claimed. Amendment of claims 35-42 and 44-46 to use "The method" and "The kit", respectively would obviate this rejection.

Claim 36 is indefinite for using the term "the step of ioslating biologically active TL-γ from a cell sample". It is unclearly how the step isolating fit into a method for screening modulators of TL-γ. It appears from claim 34 that the TL-γ is alredy isolated. Amendment of claim 36 to more particularly claim the invention would obviate this rejection.

Claims 34-42 are indefinite as there is no defined specific sequence for the claimed protein nor for a TL-γ tail domain in the claims. Without reciting a specific protein sequence, one of ordinary skill in the art cannot compare two proteins using a sequence comparison algorithm and would not be reasonably apprised of the metes and bounds of the claimed subject matter.

Claim 38 and 44 are indefinite for using the term "derived". The claims do not clearly define the way of the derivation of the TL-γ and therefore one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed subject matter.

Claim 39 is indefinite for using the term "small molecules" which is not clearly defined as what size or structure molecule would be the small molecules.

Claim 42 is indefinite for using the term "TL-γ motor domain of SEQ ID NO:1". It is not clear if the amino acid sequence SEQ ID NO:1 is the TL-γ motor domain or might indicate that the amino acid sequence of SEQ ID NO:1 is only a part of TL-γ motor domain. Amendment of

claim 42 to more particularly claim the invention, (e.g.,TL-γ motor domain having SEQ ID NO:1) would obviate this rejection.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 34, 36-39, and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Au-Young (WO 97/43413, 11/20/97).

Au-Young teaches a method for screening therapeutic compounds/modulators which interact with/modulate a biologically active PAC10 protein (page 17) and assaying for the level of the protein activity (e.g., screening a antibody that specifically binds to the protein, page 18, lines 9-10) and a change in activity between the test and control indicates a modulator (pages 17-18). The PAC10 protein is a heavy chain of the kinesin family (page 1, lines 15-19). The specification of the present invention indicates that TL-γ is also a member of the kinesin family (page 2, lines 30-32). The art teaches that a heavy chain of kinesin consists of a plus end-directed microtubule motor and a tail domain. Therefore, the PAC10 protein of Au-Young is a protein with a plus end-directed microtubule motor and a tail domain, a TL-γ protein, which has 100% identity to the motor domain of Thermomyces lanuginosus TL-γ and has identity to a TL-γ derived from Thermomyces lanuginosus. Au-Young also teaches that the biologically active

PAC10 protein is recombinant and isolated from a cell sample. Thus, Au-Young meet the all limitations of the claims.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Au-Young (WO 97/43413, 11/20/97) as applied above and Foulkes et al (US 5,580,722, Dec 3, 1996).

Au-Young teaches a method for screening therapeutic compounds/modulators which interact with/modulate a protein having TL-γ biologically active and assaying for the level of the protein activity. Au-Young does not expressly teach that the screening occurs in a multi-well plate as part of a high-throughput screen. However, Foulkes et al teach that screening for modulators of proteins occurs in a multi-well plate as part of a high-throughput screen (Abstract and column 25).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the screening method for modulators of TL-γ of Au-Young and the high-throughput screen technique of Foulkes et al because the known benefit of the high-throughput screen can be used to determine whether or not a molecule can be a modulator of protein biosynthesis and is capable of directly and specifically transcriptionally

modulating the expression of a gene encoding a protein of interest. Thus, the claimed invention as a whole was clearly *prima facie* obvious.

8. Claims 34-39, 41, and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Au-Young (WO 97/43413, 11/20/97).

Au-Young teaches a recombinant protein having TL-γ biologically active (e.g., a protein with a plus end-directed microtubule motor and a tail domain) and the protein has identity to a TL-γ derived from Thermomyces lanuginosus. Au-Young does not expressly teach a kit containing the protein. However, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to assemble together in a kit all the reagents and instructions required to perform the method because kits provide convenience and economy to the consumer and the assembly of screen-assay reagents in kit format is routine in the art.

### *Allowable Subject Matter*

9. Claim 42 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

### *Status of Claims*

10. No claims are allowed. All claims stand rejected.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee
September 6, 2000

L. F. Smith

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